

# Office Action Summary

Application No.

09/771,209

Applicant(s)

Buck et al.

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12/16/2002 and 04/21/2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 13-24, 64, and 65 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13-24, 64, and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 6) ☐ Other:

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1) Claims 1 to 8, 13 to 24, 64 and 65 are pending in the instant application. Claims 1, 6 and 8 have been amended, claims 9 to 12 have been canceled and claims 64 and 65 have been added as requested by Applicant in Paper Number 11, filed 16 December of 2002.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claim 20 stands objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for those reasons of record in section 2 of Paper Number 10. Applicant traverses this objection upon the premise that claim 20 satisfies the requirements of 37 C.F.R. § 1.75(c). 37 C.F.R. § 1.75© states that "[o]ne or more claims may be presented in dependent form, referring back to and **further limiting** another claim or claims in the same application" and "[c]laims in dependent form shall be construed to include **all the limitations** of the claim incorporated by reference into the dependent claim". Applicant has failed to explain how a claim to "a purified odorant receptor protein" **further limits** a claim to "an isolated nucleic acid molecule" and includes **all of the limitations** of the claim from which it depends. Any further response from Applicant which does not rectify this issue will be held non-responsive. See M.P.E.P. 608.01(n)III.

5) Claims 1 to 8, 13 to 24, 64 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

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as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims for those reasons of record as applied to claims 1 to 24 in section 5 of Paper Number 10. As stated therein, the only odorant receptor which is described in the instant specification in sufficient detail so as to permit an artisan to use it in a practical application is the odorant receptor identified therein as I7, which comprises the amino acid sequence presented in SEQ ID NO:76 of the instant application. The text in lines 15 to 25 on page 50 of the instant specification discloses a plurality of chemically related compounds which can be detected in a sample by employing a recombinant cell comprising a heterologous nucleic acid encoding I7. However, the instant specification does not provide the guidance needed to employ any other odorant receptor in a practical application.

Applicant traverses this rejection on the premise that “one skilled in the art could make and use the instant nucleic acids encoding the odorant receptor proteins whose sequences are set forth in the specification”. Applicant’s arguments are not persuasive because Applicant has failed to explain how one could use all of the claimed nucleic acids, or the proteins encoded thereby, in a manner that provides an immediate practical benefit to the public. As stated in the original rejection, the instant specification provides a written description of a plurality of putative receptor proteins but, with the exception of I7, does not identify any ligand for any of those receptors. In the absence of this information a practitioner can not use the claimed DNA in the manner disclosed since the ability to detect a ligand in a sample is meaningless if one does not know the identity or significance of the ligand being detected. Before a practitioner can use the

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instant invention they must first make a substantial inventive contribution by discovering a ligand for the receptor which is encoded by the claimed DNA. Because of the enormous number of possible chemical compounds which might serve as a ligand of that receptor, a practitioner would have to engage in a substantial amount of undue experimentation consisting of the screening an almost unlimited number of compounds in order to identify a receptor ligand. Since the instant application provides no guidance or working examples of a ligand for a receptor of the instant invention, beyond those compounds which bind I7, a practitioner does not have a reasonable expectation that such a ligand can be identified by simply screening large numbers of compounds. The instant specification is also devoid of guidance in predicting which compounds will serve in this capacity. Further, the need for such additional experimentation to determine how to use an claimed invention was precluded by the court when it said that “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “ [i]t is not a reward for the search, but compensation for its successful conclusion”, *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966). Because the instant specification does not provide the guidance needed to employ the vast majority of nucleic acids and proteins encompassed by the instant claims in a practical application it does not meet the “how to use” requirements of 35 U.S.C. § 112, first paragraph, for the full breadth of the instant claims. In other words, those nucleic acids that are encompassed by the instant claims and which do not encode I7 have no practical utility in currently available form.

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6) Claims 1 to 8, 13 to 24, 64 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to **make** the invention commensurate in scope with the claims for those reasons of record as applied to claims 1 to 24 in section 6 of Paper Number 10. The original rejection is based upon an analysis in accordance with M.P.E.P. 2164.01(a):

Undue Experimentation Factors

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.” These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

In responding to this rejection, Applicant does not dispute the interpretation of the breadth of the claims, the lack of working examples of intentionally modified proteins or the lack of predictability and guidance in altering those proteins. Whereas the instant specification identifies some common structural features which may distinguish odorant receptors from other members of

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the G protein-coupled receptor family, one would not reasonably believe that these common features alone are sufficient to provide those functions which define an odorant receptor. The instant claims are not limited to nucleic acids encoding naturally proteins and the proteins encoded thereby and, as stated in the original rejection, before an artisan could **predictably alter** any one of the naturally occurring amino acids sequences described in the instant specification that artisan would have to know the identity of those amino acid residues in that naturally occurring sequence which are critical to the structural and functional integrity of an odorant receptor comprising that sequence and those residues which are expendable. Because the instant specification does not identify those amino acid residues in even one of the twenty three amino acid sequences described therein which are critical to the structural and functional integrity of an odorant receptor protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to an odorant receptor protein by extrapolation, or even provide a single working example of an intentionally modified protein of the instant invention, an artisan can not change even a single residue within any one of the twenty three naturally occurring the amino acid sequences presented in the instant specification and predict the effects of that change on the performance of that protein "by resort to known scientific law".

7) Claims 1 to 8, 13 to 24, 64 and 65 are 1 to 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Zhao et al. publication (SCIENCE 279:237-242, 09 Jan. 1998, cited by Applicant) for those reasons of record as applied to claims 1 to 24 in section 7 of Paper Number 10.

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8) Claims 1 to 8, 13 to 18 , 20, 64 and 65 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Buck et al. publication (Cell 65:175-187, 1991) for those reasons of record as applied to claims 1 to 18 and 20 in section 8 of Paper Number 10. Applicant asserts that claim 65 is distinct from the Buck et al. publication because it recites features not disclosed by Buck et al. Applicant is advised that the protein encoded by the nucleic acid described by Buck et al. is elected species of protein of the instant invention. If claim 65 does not encompass the elected embodiment of the instant invention then it is withdrawn from consideration as being drawn to a non-elected species. Applicant was advised at the time of the original restriction requirement that “ [i]f claims are added after the election, **applicant must indicate** which are readable upon the elected species” (emphasis added). See MPEP § 809.02(a). If claim 65 does encompass the elected invention, then it is anticipated by the Buck et al. publication.

Applicant has traversed both of the above rejections on the premise that Zhao et al. and Buck et al. are not available under 35 U.S.C. 102(b) because the now claimed subject matter was “fully disclosed” in application Serial Number 08/129,079. Whereas the claimed subject matter was certainly described in that prior application, that application failed to disclose **how to use** the claimed subject matter in a specific and practical application in its currently available form, as required by the first paragraph of 35 U.S.C. § 112. Therefore, that application is unavailable under 35 U.S.C. § 120 for the now claimed subject matter.

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9) Claims 19 and 21 to 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Buck et al. publication (Cell 65:175-187, 1991) for those reasons of record in section 9 of Paper Number 10.

10) Applicant's arguments filed 16 December of 2002 have been fully considered but they are not persuasive for those reasons given above.

11) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800